

# (12) UK Patent Application (19) GB (11) 2 290 972 (13) A

(43) Date of A Publication 17.01.1996

(21) Application No 9506203.0

(22) Date of Filing 27.03.1995

(30) Priority Data

(31) 9414049	(32) 12.07.1994	(33) GB
9422914	14.11.1994	
9424066	29.11.1994	

(51) INT CL<sup>6</sup>

A61F 5/453

(52) UK CL (Edition O )

A5R RCED R321

(56) Documents Cited

GB 2278279 A US 5205298 A

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(58) Field of Search

UK CL (Edition N ) A5R RCED REYJ REYK

INT CL<sup>6</sup> A61F 5/453 6/00 6/04

Online: WPI

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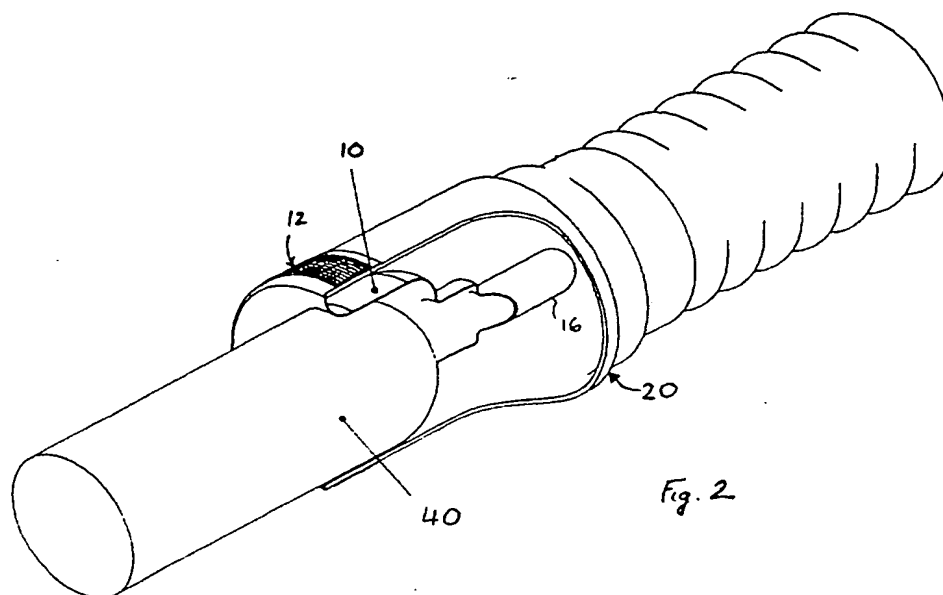
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## (54) Male incontinence sheath and applicator

(57) A male incontinence sheath is applied by putting the sheath 10 onto the open end of a bellows 20 and placing the device on the penis 40, the bellows is compressed, the air exiting through a one-way valve, the bellows is then expanded creating a partial vacuum which draws the sheath and penis into the bellows. Air is then admitted into the bellows causing the sheath to collapse onto the penis. The bellows is then pushed towards the wearer, causing the sheath to be everted as it slides off the bellows onto the penis. A ring of adhesive 12 secures the sheath to the penis. The bellows can then be removed and discarded. Alternatively, the bellows may be reused if used together with a removable sleeve carrying the sheath. The bellows may be replaced by a pair of telescoping tubes.



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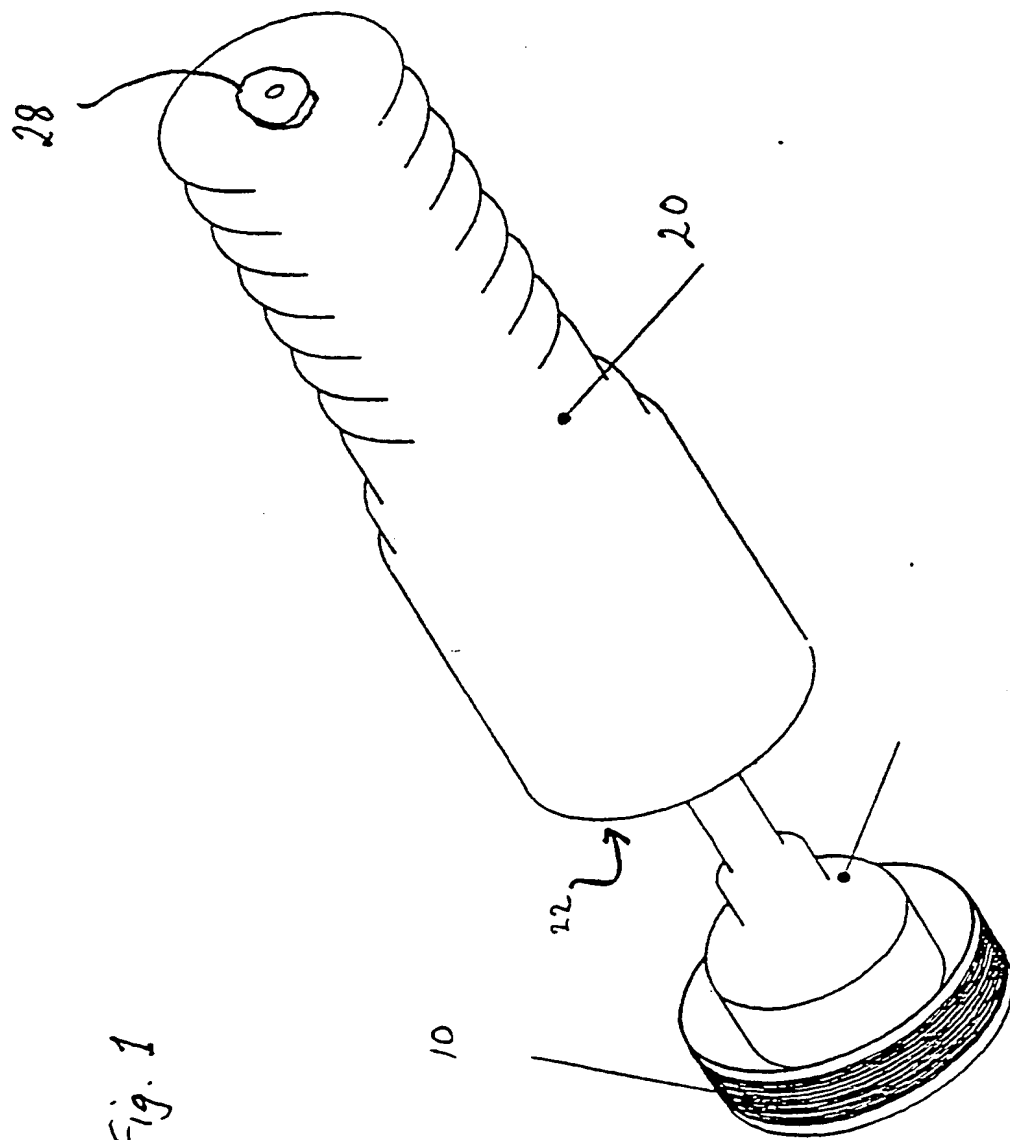


Fig. 1

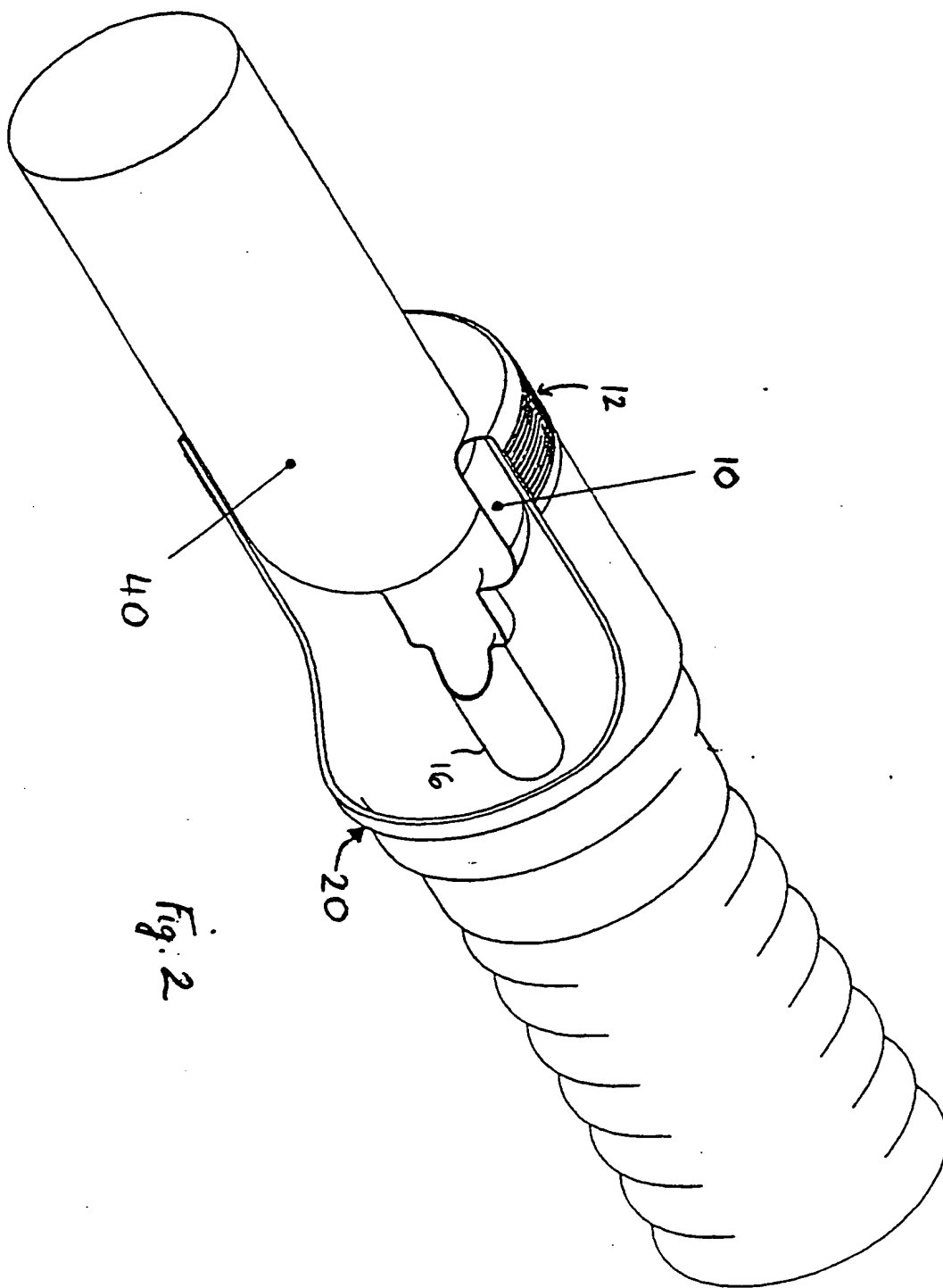


Fig. 2

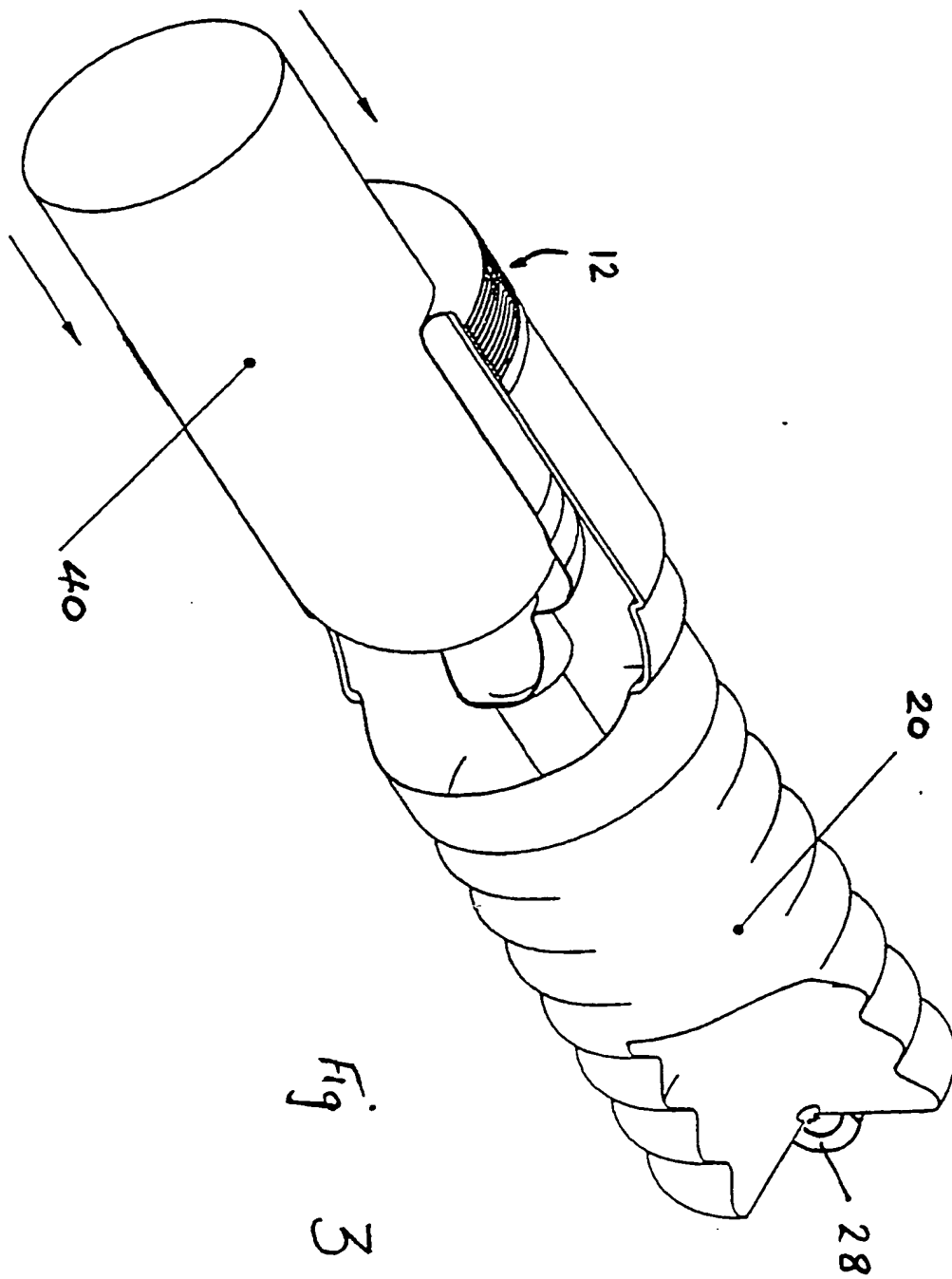


Fig. 3

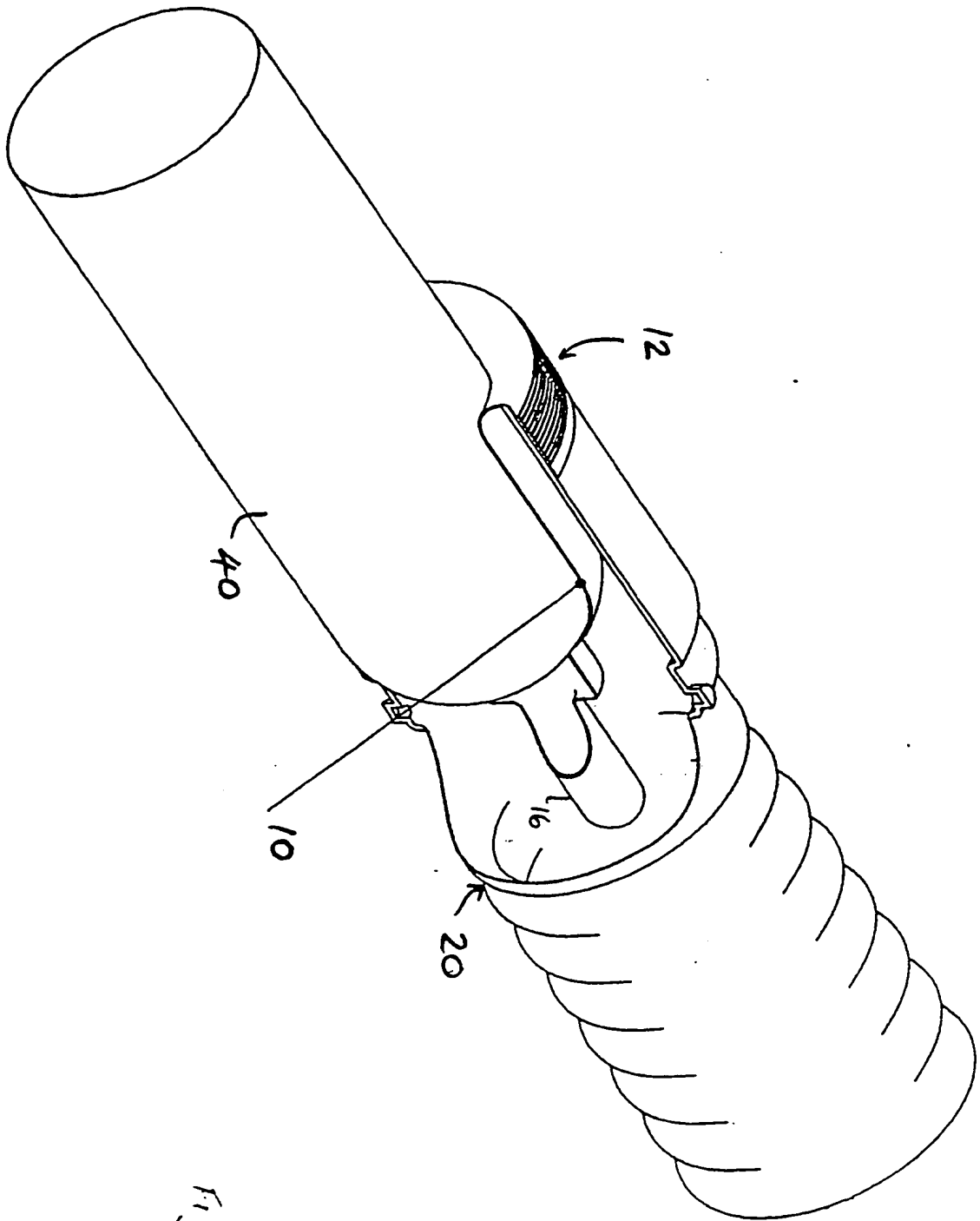


Fig. 4

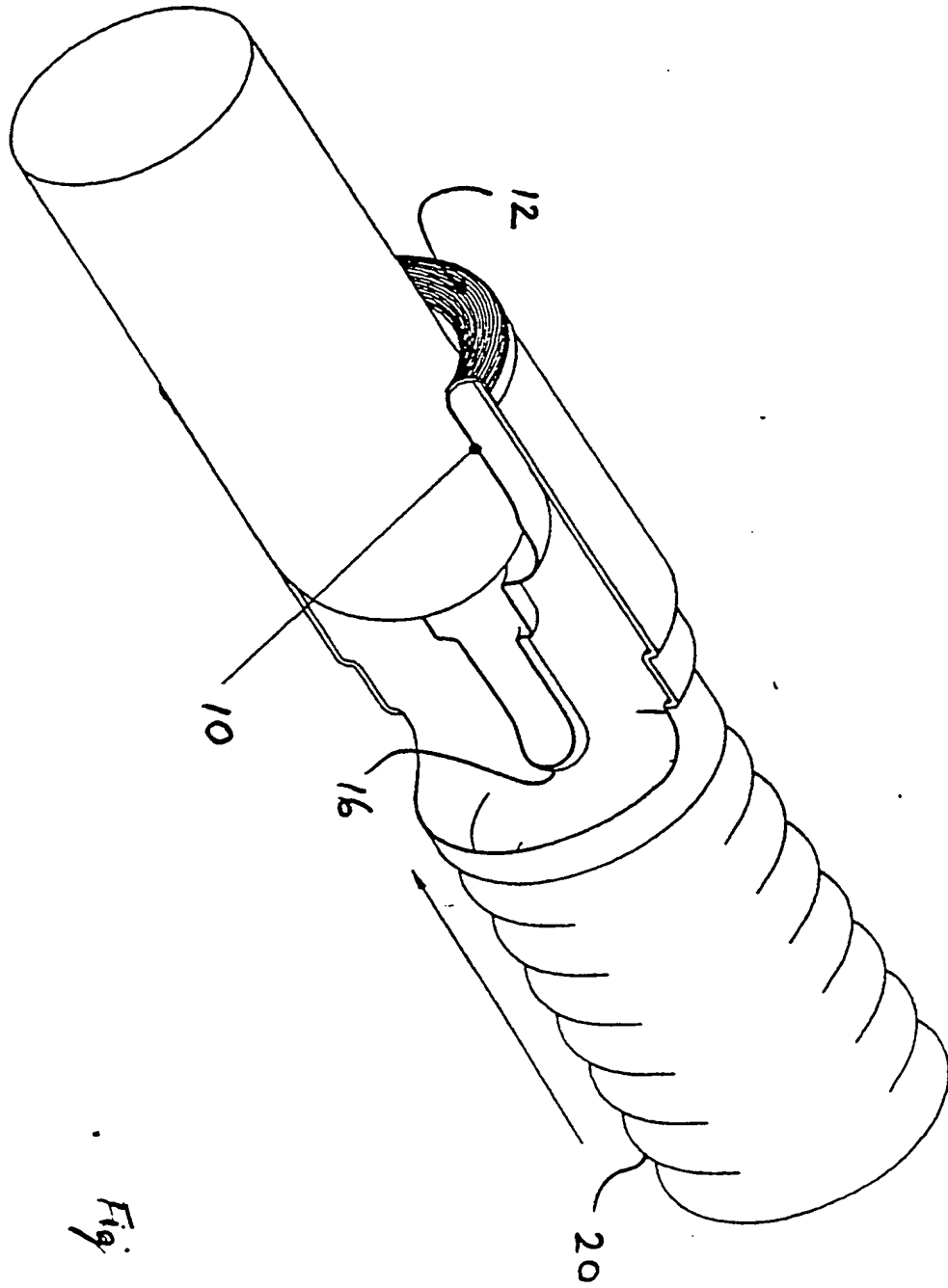


Fig 5

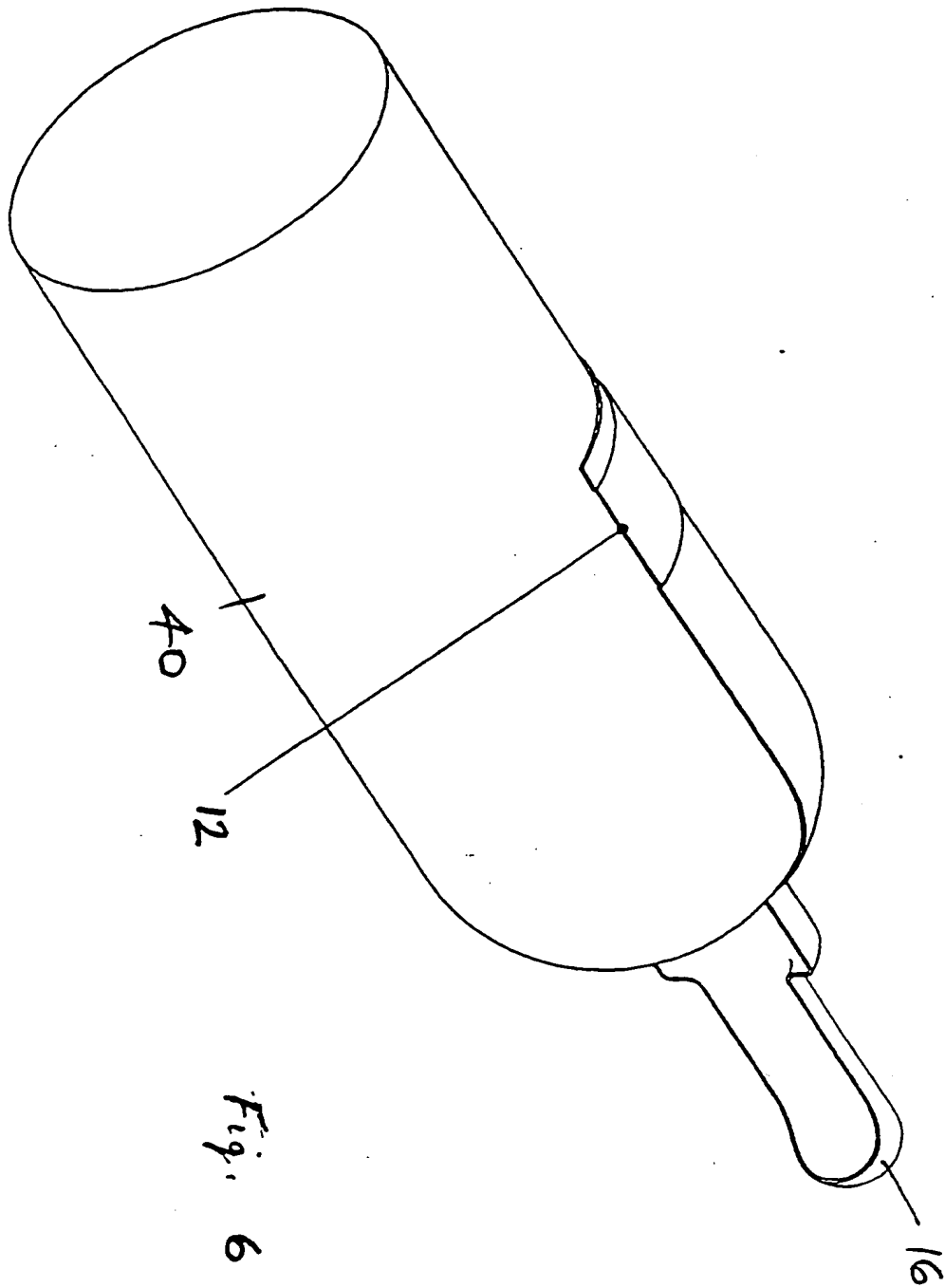


Fig. 6

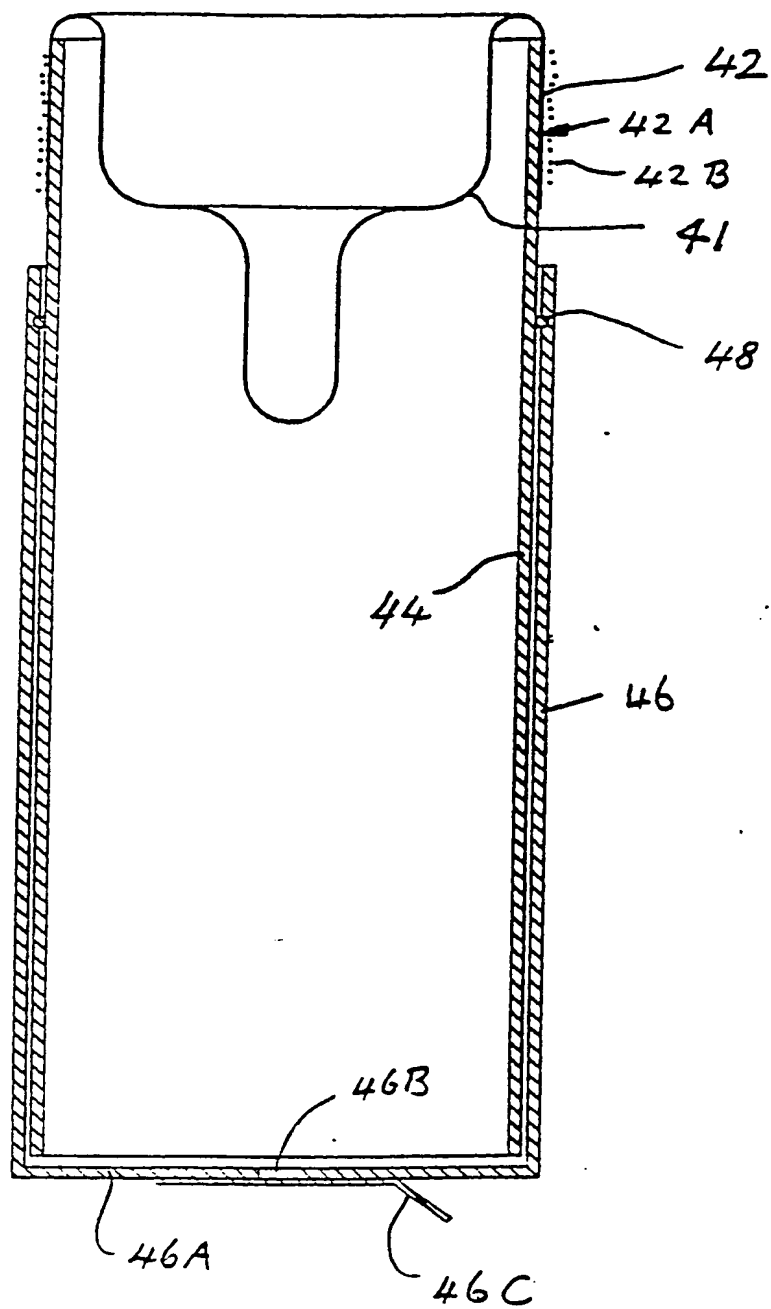


Fig. 7

↓ A



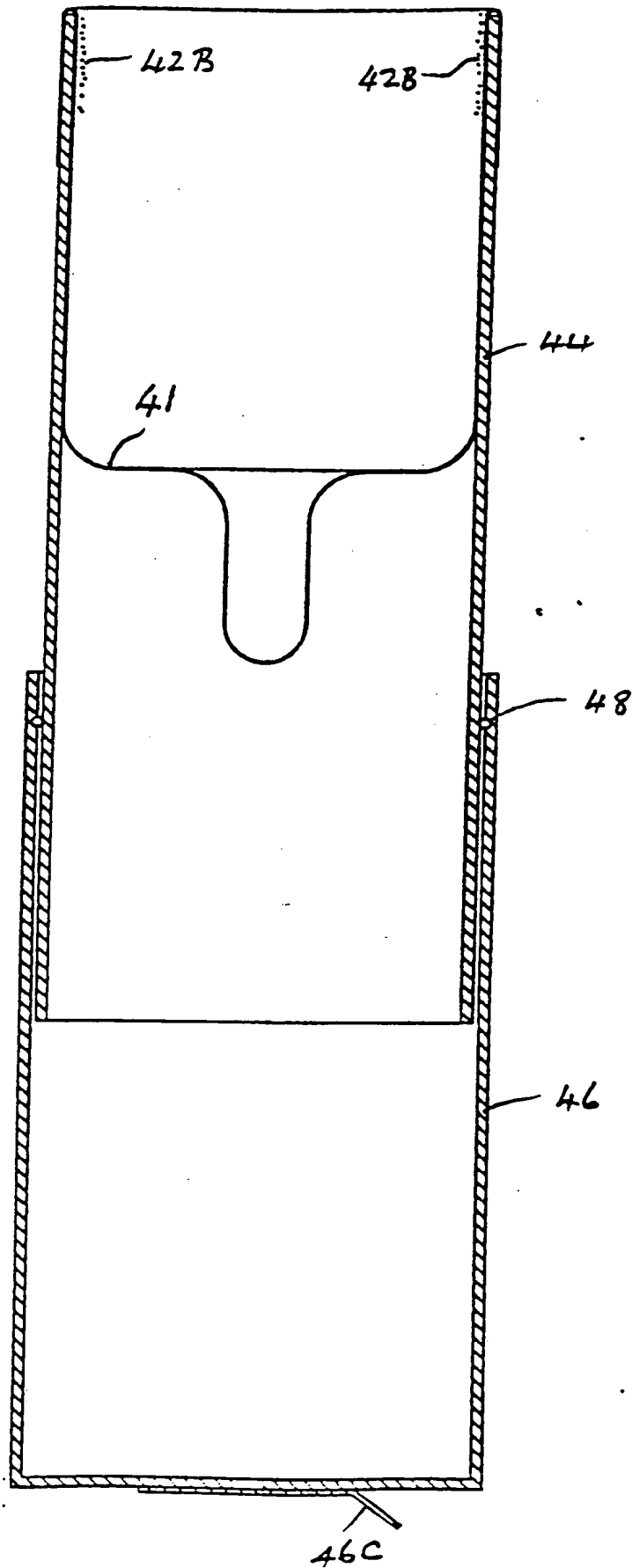


Fig. 8

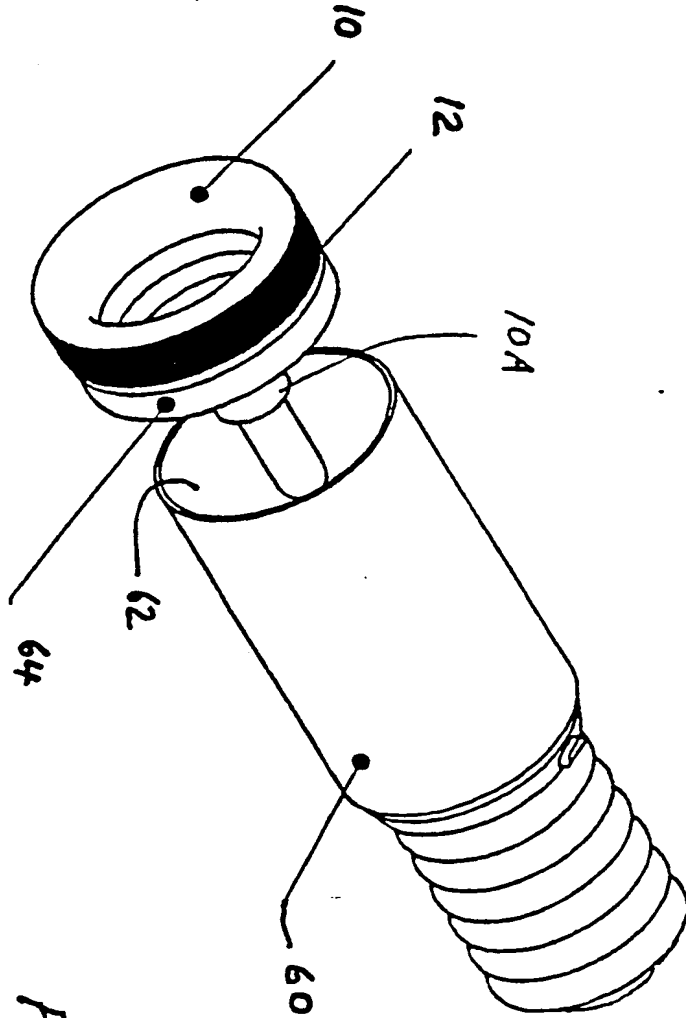


Fig. 9

MALE INCONTINENCE SHEATH AND APPLICATOR

This invention relates to a male incontinence sheath and applicator.

Male incontinence devices are well known. It is also known to expand a condom before application by negative pressure (see GB 2 206 793A, USP 5 205 298, U.S. Patent 4 961 734 of Kassman and U.S. Patent 4 984 582 of Romaniszyn) and to similarly expand an incontinence sheath (see e.g. European Patent Application No.(EP-A)97521; EP 325902A; PCT-WO81/03609 of Brendling; and GB 2 254 560A which shows everting the sheath. Applications for incontinence sheaths are also numerous in the prior art, see for example GB 2 120 102A and USP 5 275 587. The art is replete with other suggestions for the design of male incontinence devices. The function of such a device is to serve an entirely different and more long-term purpose than a condom.

Many of the prior art patentees in the field claim that their devices are easy to apply. Yet in the present Applicant's opinion, no male incontinence device which is truly easy to apply as well as being comfortable and reliably attached has yet been suggested. One of the important factors, to the nurse, is that it should not be necessary to obtain a separate applicator, or accurately manipulate multiple components, in order to apply the device to the penis. With the ever-increasing costs of running the National Health Service (in U.K.) and like services in other countries, it is of course highly desirable that routine tasks such as the application of incontinence devices should be done with the maximum expedition in order to efficiently use nurses' time. To the best of Applicants' knowledge and belief, there is not yet available a male incontinence device in a single package which contains all that is necessary to satisfactorily (and quickly) apply a urinary sheath to a penis. Still less is there available one which can be satisfactorily and quickly applied to a seriously retracted penis.

According to one aspect of the invention, there is provided a male incontinence device including a condom-like sheath of thin resilient material, e.g. a rubber latex or a polyurethane film, the

sheath carrying an annular layer of adhesive at or near its open end, an expansible substantially cylindrical bellows, a non-return valve on the bellows, and means for allowing the ambient atmosphere into the interior of the bellows.

5           According to another aspect of the invention, there is provided a method of applying a condom-like sheath to the penis which comprises the steps of:-

10           (a) assembling the sheath with its open end folded over the open end of a bellows, said bellows having the remainder of the sheath located therein, the folded-over end of the sheath having a ring of adhesive thereon which is external when folded over;

          (b) applying the sheath, carried by the bellows, endwise onto the penis;

15           (c) causing the bellows to expand longitudinally, so causing the sheath to be expanded due to the reduction in pressure consequent upon the expansion of the bellows and the penis to be sucked further into the sheath;

20           (d) causing or allowing ambient atmosphere to enter the bellows via the non-return valve, whereby the sheath collapses to snugly envelop the penis;

          (e) pushing the bellows-sheath combination endwise of the penis so that the bellows slides relative to the sheath whose open end portion is thereby caused to evert so that its ring of adhesive encircles and comes into contact with the penis shaft, and

25           (f) removing the bellows, leaving the sheath in place on the penis.

30           According to a further embodiment of the invention, there is provided a product for use in applying a urinary sheath to a penis without the need for a nurse or other caring person to handle the penis, said product comprising a bellows having a tubular open end and an end closed by a non-return valve, a urinary sheath located on the open end of the bellows with an open end portion of the sheath folded over the open end of the bellows and carrying a ring of adhesive on a part of the surface exposed by said folding-over, the  
35           bellows being operable so that it can be compressed against its own

resilience and expanded to suck the head of a penis at least part way into the open end of the sheath.

The invention will be better understood from the following description of an example thereof, given with reference to the accompanying drawings, in which like parts are denoted by like reference numerals and in which:-

Figure 1 is an exploded view of one example of male incontinence device according to the invention;

Figure 2 illustrates a urinary sheath and an applicator being applied, e.g. by a nurse (not shown), to the penis of a patient;

Figure 3 shows the head of the penis being drawn in to the open end of the bellows as the bellows is expanded, a non-return valve being mounted on the end of the bellows;

Figure 4 shows the sheath collapsing upon, and snugly engaging the penis;

Figure 5 illustrates the bellows being withdrawn and the sheath sliding off the penis;

Figure 6 shows the urinary sheath with its open end everted and in its final position on the penis, the adhesive annulus now being internal of the sheath and in contact with the penis shaft;

Figure 7 is a longitudinal cross-section view through a male incontinence device according to an alternative embodiment of the invention;

Figure 8 is a view similar to Figure 7 but showing the device in its extended condition; and

Figure 9 is a perspective view of a male incontinence device which is similar to that described in the embodiment illustrated in Figures 1-6, but which has a separate ring or collar which initially carries the sheath.

Referring firstly to Figures 1 and 2 of the accompanying drawings, there is shown a condom-like urinary sheath 10 and a bellows 20. The urinary sheath 10 has a large open end 14 and an outlet tube 16 at the other end. It has adhesive 12 on its inner surface as seen in Figures 2 and 3. The end 14 is referred to herein as the "open end". The bellows 20 has an open end 22. A non-return valve 28 is located in the free end of the bellows 20 (see Figure 3).

The non-return valve 28, when actuated, permits ambient air to enter the bellows for a purpose which will be described below. The assembly shown in Figure 1 may in practice have a diameter of about 30-40 millimetres and a length of about 50-80 millimetres. Of course other dimensions may be used without departing from the invention.

The manner of use of the urinary sheath and applicator illustrated will now be described with reference to Figures 2-6.

Starting with the product shown in Figure 1, the first step is to apply the bellows 20 gently onto the penis 40, which, if flaccid or partly retracted, may only be entered part-way into the open end of the bellows 20, as shown in Figure 2. The next step is to compress the bellows. This can be done by pressing on the end of the bellows 20 which carries the valve 28, so placing the bellows in a temporarily contracted condition. With the non-return valve 28 closed, the bellows is manually expanded. The expansion of the bellows 20 is assisted by its own resilience, so causing a reduced pressure within the bellows which in turn causes a distension of part of the sheath 10. The partial vacuum within the sheath which arises tends to suck the penis 40 into the sheath. As seen in Figure 5, the peripheral wall of the urinary sheath is distended so that it is in contact with or near to the interior surface of the open end 22 of the bellows 20. At this time, the valve 28 is still closed.

The next step is to open the non-return valve 28 which permits ambient atmosphere to enter the bellows 20 and so permits the portion 10A of the sheath to collapse radially inwardly and snugly envelop the head of the penis. Then the bellows 20 is manually pushed towards the wearer of the incontinence device. By this action, the completion of the insertion of the penis into the sheath is achieved. This pushing action causes the urinary sheath 10 to be everted as it slides off the open end portion 22 of the bellows 20 as seen in Figure 5. The adhesive 12 on the sheath 10, which now faces inwardly, makes adhesive contact and attaches the sheath to the penis 40 as seen in Figure 6. Once the open end portion of the urinary sheath 10 has everted, the bellows 20 is removed in a direction towards the right as seen in Figure 5 and may be discarded. The adhesive area of the sheath may if necessary be gently pressed onto

the penis. As seen in Figure 6, the urinary sheath 10 is then comfortably attached to the penis 40 and a drain tube may be secured as required to the smaller diameter open end 16.

5 It will be seen that the necessary manipulation to apply the urinary sheath 10 to the penis is very easily and quickly done. In particular, the distension of the sheath 10 makes it easy to insert or draw the head of the penis into the applicator 20. The invention has the considerable advantages that it can cope with those having a retracted penis and that nurses do not have to handle the penis at  
10 any time in the application procedure.

An alternative embodiment of the invention is shown in Figures 7 and 8. The male incontinence device illustrated comprises a urinary sheath 41 which has its free end 42 folded over one open end of a tubular sleeve 44. The sleeve 44 may be made of any suitable  
15 relatively rigid material, e.g. a synthetic plastics or cardboard. The surface 42A of the sheath end 42 carries a ring of adhesive 42B. This ring encircles the sheath and may have an axial length of about 10 to about 25 mm. The sleeve 44 is preferably circular in transverse cross-section and extends into a complementary  
20 substantially closed-ended sleeve 46 whose inside diameter is slightly less than the outside diameter of the inner sleeve 44. The latter has a diameter of a few millimetres larger than that of an average penis. An O-ring 48 is located within a groove 50 which extends around the inside surface of the sleeve 44, and engages the  
25 outer surface of the sleeve 46. The closed end 46A of the sleeve 46 has a hole 46B therein which is covered by a removable closure member 46C. This may for example be an adhesive patch.

In use, the urinary sheath 41 is fitted on the end of the sleeve 44. The sleeve 46 is then withdrawn in the direction of arrow  
30 A so causing a reduction of pressure within the space defined by sleeves 44 and 46. This causes the sheath 41 to be stretched and move towards the inner surface of the sleeve 44 as shown in Figure 8. The device is then placed over the penis and the closure member 46C removed. This allows the sheath to contract under its own  
35 elasticity and to snugly surround the penis, with the adhesive 42B (Fig.8) coming into contact with the penis to hold the sheath

securely on the penis.

5 A further alternative embodiment of the invention is shown in Figure 9. This is a perspective view of a male incontinence device which is similar to that described in the embodiment illustrated in Figures 1-6 in that it comprises a bellows 60, having a non-return valve, not shown, located similarly to the non-return valve of Figures 1-6. According to this embodiment of the invention, the bellows 60 is open-ended, and carries at its open end 62 (the left hand end in the drawing) a removable further sleeve or cylindrical annular ring 64. This ring sleeve 64 is designed to carry a condom-like sheath 10 which has its main part 10A extending through the centre of the sleeve 64 and into the bellows 60, when the sleeve 64 is attached to the end of the bellows 60. The open end of the sheath 10 is initially folded over the sleeve 64 in the manner shown, with a layer of adhesive 14 located in a radially outwardly facing manner. The sleeve 64 may be connected to the bellows by a push-in fit achieved by appropriate dimensioning of the parts, or by a threaded connection (the threads not being shown). Other ways of removably fixing the sleeve 64 to the bellows 60 will occur to a man skilled in the art.

10 In use, with the sleeve 64 connected to the bellows 60 in any convenient way, the device is operated in the same way as that previously described in connection with Figures 1-6. However, this embodiment of the invention has the advantage that the bellows 60 carrying the non-return valve can be readily removed from the sleeve 64, and is reusable. This being the case, the only disposable item is the sleeve 64, hence leading to a reduction in the cost of the product.

15 Any suitable adhesive may be used as the layer 14 or 42B. For example, one suitable adhesive is described in U.S. Patent No. 5 176 666.

20 As will be seen from the foregoing, the embodiments of the invention enable an incontinence device to be reliably attached to the wearer without the nurse having to handle his penis.



## CLAIMS

1. A male incontinence device comprising a condom-like sheath of thin resilient material such as a rubber latex or a polyurethane film, the sheath carrying an annular layer of adhesive and being mounted on a sleeve element, an expansible substantially cylindrical bellows connectable to or integral with said sleeve element, and a means for controllably allowing the ambient atmosphere into the interior of the bellows.

2. A method of applying a condom-like sheath to the penis which comprises the steps of:-

(a) assembling the sheath with its open end folded over the open end of a bellows, said bellows being in a contracted condition and the remainder of the sheath being located therein, the folded-over end of the sheath having an external ring of adhesive thereon;

(b) applying the sheath, carried by the bellows, endwise onto the penis;

(c) causing the bellows to expand longitudinally, so causing the sheath to be expanded due to the reduction in pressure consequent upon the expansion of the bellows and the penis to be sucked further into the sheath;

(d) causing or allowing ambient atmosphere to enter the bellows, whereby the sheath collapses to snugly envelop the penis, either before or after or simultaneously with step (e);

(e) pushing the bellows-sheath combination endwise of the penis so that the bellows slides relative to the sheath whose open end portion is thereby caused to evert so that its ring of adhesive encircles and comes into contact with the penis shaft, and

(f) removing the bellows, leaving the sheath in place on the penis.

3. A method according to claim 2 in which the ring of adhesive is on the external surface of a folded-over end portion of the sheath and extends an axial distance of approximately 10 mm to 25 mm.

4. A product for use in applying a urinary sheath to a penis without the need for a nurse or other caring person to handle the penis, said product comprising a bellows having a tubular open end and an end closed by a non-return valve, a urinary sheath located on the open end of the bellows with an open end portion of the sheath folded over the open end of the bellows and carrying a ring of adhesive on a part of the surface exposed by said folding-over, the bellows being operable so that it can be compressed against its own resilience and expanded to suck the head of a penis at least part way into the open end of the sheath.

5. A product according to claim 4 further including a removable ring or sleeve connectable to the open end of the bellows.

6. A method according to claim 2 or 3 modified in that the bellows is open at one end, and said one end is constructed to receive an annular sleeve which carries the sheath with its open end folded thereover, the sleeve being connectable to and disconnectable from the open end of the bellows.

7. A male incontinence device including a tubular (first) sleeve telescopically slidable relative to a second sleeve having an open end and an end closed by a removable closure member, the first sleeve carrying a urinary sheath.

8. A male incontinence device according to claim 7 in which the first sleeve is connectible to a second sleeve which carries a urinary sheath with its open end folded over the outer surface of the second sleeve, the second sleeve being detachably mountable on the first sleeve.

9. A method of applying a urinary sheath to the penis which comprises placing the sheath on a first sleeve, telescopically extending a second sleeve relative to the first sleeve to expand the sheath, placing the expanded sheath still carried by first sleeve over the penis, and allowing ambient atmosphere to enter the second

sleeve so causing the sheath to collapse onto the penis.

10. A device according to claim 1 in which the means for controllably allowing ambient atmosphere into the interior of the bellows comprises a non-return valve.

11. A urinary incontinence product substantially as herein described with reference to and as illustrated in Figures 1-6, or Figures 7 and 8, or Figure 9 of the accompanying drawings.

12. Any novel combination or sub-combination of features disclosed and/or illustrated herein.

**Relevant Technical Fields**

- (i) UK Cl (Ed.N) A5R (RCED, REYJ, REYK)  
 (ii) Int Cl (Ed.6) A61F 5/453, 6/00, 6/04

**Databases (see below)**

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 (ii) ONLINE: WPI

Search Examiner  
 MR N A FRANKLIN

Date of completion of Search  
 31 AUGUST 1995

Documents considered relevant  
 following a search in respect of  
 Claims :-  
 1-6, 10, 11 (part)

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E,X	GB 2278279 A (E R SQUIBB) note page 5 lines 19-23	1
X	US 5205298 (HURST) note entire document	1, 2, 4 at least

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